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IN THE UNITED STATES COURT OF FEDERAL CLAIMS
Washington, D.C.

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U.S. COURT OF
FEDERAL CLAIMS

BID PROTEST

ACETRIS HEALTH, LLC, Plaintiff, v. UNITED STATES, Defendant.	CFC No. 18-433 C Judge _____

COMPLAINT FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF AND A DECLARATORY JUDGMENT

Plaintiff Acetris Health, LLC ("Acetris" or "the Company"), by its undersigned attorneys, does for its Complaint in this action hereby state and allege as follows:

I. NATURE OF THE CASE

1. This complaint is in the nature of a pre-award bid protest for declaratory and injunctive relief arising from the Department of Veterans Affairs' ("VA") erroneous interpretation of the Trade Agreement Clause ("TA Clause"), 48 C.F.R. 52.225-5, of Solicitation No. 36E79718R0019 ("the Solicitation") for the purchase of Entecavir Tablets, contrary to the Federal Acquisition Regulation ("FAR"). Entecavir Tablets are prescription drugs used for the treatment of Hepatitis B.

2. Acetris' Entecavir Tablets are commercial off-the-shelf products manufactured by its supplier in Dayton, New Jersey, and therefore qualify as "domestic end products" and "U.S.-made end products" as those terms are defined in FAR Part 25 – Foreign Acquisitions. 48 C.F.R. 25.003. Every manufacturing activity necessary to

manufacture this drug from active and inactive ingredients sourced in the United States, India and other countries occurs in the United States.

3. FAR Part 25 – Foreign Acquisition implements the Buy American Act ("BAA"), 41 U.S.C. 8301 *et seq.*, and the Trade Agreements Act ("TAA"), 19 U.S.C. 2511-2518, which are interrelated, and, when the TAA applies, restricts acquisition of foreign end products to eligible foreign products not subject to discriminatory treatment due to various trade agreements. Products that qualify as domestic end products are a subset of U.S.-made end products and cannot, by definition, be "noneligible products," as noneligible products are "foreign end products," which are products "other than domestic end products." 48 C.F.R. 25.003. U.S.-made end products that do not qualify as domestic end products are treated as foreign end products unless the TAA applies. 48 C.F.R. 25.504-1, 25.504-2.

4. For purposes of FAR Part 25 – Foreign Acquisition, and the TA Clause implementing the regulation, an end product is a U.S.-made end product if it is one "that is manufactured in the United States, or that is substantially transformed in the United States into a new and different article of commerce with a new name, character, or use distinct from that of the article or articles from which it was transformed." 48 C.F.R. 25.003 (emphasis added).

5. When the TA Clause applies, the government can purchase U.S.-made end products, including domestic end products, and foreign end products of designated countries eligible for a waiver of BAA preferences under the TAA. 48 C.F.R. 25.504-2.

6. The VA's interpretation of the TA Clause and related Trade Agreements Certificate in 48 C.F.R. 52.212-3 requires Entecavir Tablets manufactured in the United States also to

be substantially transformed in the United States in order to comply with the Clause, if they contain foreign components. This interpretation impermissibly reads out the obligation of the contracting officer to consider U.S.-made end products that satisfy the first of two alternate criteria in the regulation and the TA Clause, *i.e.*, they are manufactured in the United States, regardless of whether those products contain foreign components, or are substantially transformed in the United States or elsewhere, the alternate criterion. Under the plain language of the regulation and the TA Clause, products need not qualify under the second criterion if they qualify under the first criterion.

7. If not enjoined, this interpretation will prohibit Acetris' offer of U.S.-made products manufactured in the United States under the Solicitation in violation of the FAR. Alternatively, if the VA treats Acetris' product as a "noneligible product," defined in FAR 25.003 as a foreign end product that is not an eligible product, and determines that there are no other offers of TA Clause compliant products, then the VA may make an improper non-availability determination, inviting offers of noneligible products and depriving Acetris' product of the mandatory preference afforded U.S.-made end products by U.S. procurement regulations.

8. In determining compliance of a product with the TA Clause, the VA relies on United States Customs and Border Protection ("CBP"), which has authority under the TAA to issue final determinations regarding country of origin of foreign products under the standard for determining designated country products, which is different than the standard for determining U.S.-made end products in the TA Clause. It is VA policy not to make a separate determination under the TA Clause of whether a product is

manufactured in the United States and thus a U.S.-made end product eligible for purchase by the government under the TA Clause.

9. For all these reasons, this complaint requests (1) a declaration that the Solicitation's TA Clause permits the government to purchase U.S.-made Entecavir Tablets manufactured in the United States and that the VA's interpretation of the TA Clause is arbitrary and capricious and in violation of the FAR, and (2) injunctive relief prohibiting the VA from imposing an interpretation of the TA Clause in the Solicitation as requiring Entecavir Tablets be substantially transformed in the U.S. before they can be considered U.S.-made end products and TA Clause compliant, if the Tablets are manufactured in the United States, and prohibiting the VA from treating Acetris' Entecavir Tablets manufactured in the United States as noneligible products under the TA Clause.

II. PARTIES

10. Acetris is a corporation organized under the laws of Delaware, with a principal place of business at Park 80 West, 250 Pehle Avenue, Saddle Brook, NJ, 07663. Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the federal government. Among the products Acetris sells to the federal government are Entecavir Tablets, which are a guanosine nucleoside analogue with selective activity against Hepatitis B virus ("HBV").

11. Defendant is the United States of America, its agents, officers and employees in their official capacities, acting through the VA.

III. JURISDICTION

12. Jurisdiction in this Court is based on the Tucker Act, 28 U.S.C. § 1491(b)(1). This case arises out of solicitation by a Federal agency for bids or proposals for a proposed

contract and violation of law and regulation in connection with a procurement. Acetris objects to the VA's issuance of the Solicitation under which the agency will treat the Company's U.S.-made end products manufactured in the United States as non-compliant with the TA Clause, in violation of the FAR.

13. The remedies sought are authorized by the Tucker Act, 28 U.S.C. § 1491(b)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

14. Acetris is an interested party under 28 U.S.C. § 1491. The Company holds current VA Contract No. VA797P-17-C-0011 for the purchase of Entecavir Tablets, has the capability to meet the government's needs under the Solicitation, and is fully prepared to submit an offer in response to the Solicitation.

15. Acetris has a substantial chance of receiving an award if the protest is sustained. The Company's direct economic interest is therefore affected.

IV. STATEMENT OF FACTS AND GENERAL ALLEGATIONS

Manufacture of Entecavir Tablets in the United States

16. Section 13 of the Solicitation requires the offeror to identify the place of manufacture of the end product – Entecavir Tablets – and specifies, for capsules and tablets, the place of manufacture is the location "where ingredients are measured, weighed, mixed and compounded." Complaint Ex. 1, Solicitation. For Acetris' Entecavir Tablets, these manufacturing processes all occur in Dayton, New Jersey.

17. Acetris' Entecavir Tablet end product is manufactured for Acetris by Aurolife Pharma LLC in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, United States, through a complicated manufacturing process that involves the combination of active and inactive ingredients,

including some intermediates that are mixed in to aid the conversion of the multiple ingredients and ensure the safety and effectiveness of the resulting end product for use as a drug. Complaint Ex. 2, Declaration of Venkat Kota.

18. Abbreviated New Drug Application ("ANDA") No. 206217, under which the FDA has approved the marketing of Entecavir Tablets, specifies the exact formulation that must be mixed, and the manufacturing processes that must be followed, in order for the Entecavir Tablets authorized by the ANDA to be marketed for use as a prescription drug. *Id.* The manufacturing of Entecavir Tablets employs processes that transform these ingredients into finished, medically safe and effective dosage tablets. *Id.*

19. The process of converting these multiple ingredients into the Entecavir Tablets occurs entirely within the United States. *Id.*

20. The ingredients processed in the United States are sourced from a variety of suppliers, both U.S. and foreign, including, among other ingredients: Lactose Monohydrate; Microcrystalline Cellulose; Crospovidone; Magnesium Stearate; Aquarius BP18257 cool Vanilla IH; and the active ingredient, entecavir. *Id.*

21. It is highly important to formulate a stable drug product that maintains desired physico-chemical properties and adequate content uniformity resulting in the desired pharmacological effect upon administration, which the Aurolife drug product does. *Id.* Extensive additional processing of the active ingredient with other ingredients must occur to produce a stable drug product that achieves the targeted disintegration and dissolution and exhibits appropriate physico-chemical properties including the desired pharmacokinetics and therapeutic efficacy. *Id.*

22. The multiple components utilized in the U.S.-based manufacturing process for Entecavir Tablets include the following:

23. Lactose Monohydrate Microcrystalline Cellulose are added as bulking agents for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication. These diluents also aid in achieving desired uniformity with the help of processing steps like co-sifting. *Id.*

24. Crospovidone is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Baraclude®) for therapeutic equivalency as required by the applicable FDA-approved ANDA. *Id.*

25. Magnesium stearate is added to create a hydrophobic environment around particles, which provides a lubrication effect during the manufacturing process. Lubricant mixing is carefully done to ensure that the drug release profile and pharmacokinetics is not influenced by this hydrophobic environment. *Id.*

26. Film coating agent is added to give each strength a distinct character. Film coating is performed using polymers, which imparts and gives a protective barrier for each strength of the drug, making it appropriate for patient use. *Id.*

27. Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes, thereby producing a more stable Drug Product whose therapeutic effectiveness as a drug is sustainable. *Id.*

28. Manufacturing of Entecavir Tablets includes the following separate processes, all of which occur within the United States, that transform the active and inactive ingredients

into Entecavir Tablets: testing of raw materials for potency; weighing the raw materials for discharge; sifting of intra-granular materials; dry mixing; granulation; drying; sifting and milling; sifting of extra-granular materials; blending and lubrication; compression; coating dispersion preparation; coating; and packing and labeling. *Id.*

29. These processes require complex and expensive pieces of large-scale, industrial equipment costing hundreds of thousands of dollars. *Id.*

30. The time necessary to manufacture each batch of Entecavir Tablets is quite substantial and requires up to several days per batch. *Id.*

31. The manufacturing process in the United States adds significant value to the Entecavir Tablets, far beyond the standalone value of the active and inactive ingredients. *Id.*

32. The Entecavir Tablets are commercial off the shelf ("COTS") products as defined in FAR 2.101.

The Trade Agreement Act of 1979

33. The Trade Agreements Act, 19 U.S.C. 2511-2518, permits the President to waive, with respect to eligible products of certain foreign countries, discriminatory purchasing requirements that otherwise would disfavor those products. 19 U.S.C. 2511.

34. An item is a product of a designated foreign country under one of two circumstances: "(i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed." 19 U.S.C. 2518.

35. The TAA creates a mechanism for administrative determination of country of origin under the TAA. This mechanism is implemented at 19 C.F.R 177.21 *et seq.* Mirroring the TAA, the regulations provide that "an article is a product of a country or instrumentality only if (1) it is wholly the growth, product, or manufacture of that country or instrumentality, or (2) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed."

The Trade Agreements Clause, 48 C.F.R. 52.225-5 and Related Certificate

36. The TA Clause, 48 C.F.R. 52.225-5, is different from the TAA. The TA Clause addresses which products the United States can buy with appropriated funds without a non-availability determination. Specifically, it requires the government to buy "U.S.-made end products" or "designated country end products" unless there are no offers for such products.

37. The "designated country end product" portion of the clause is intended to implement the TAA waiver for certain products of designated (foreign) countries. It permits the government to purchase an article that (a) is wholly the growth, product, or manufacture of a designated country; or (b) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a designated country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The United States is not a designated country.

38. The U.S.-made end product portion of the TA Clause is separate, and not derived, from the TAA, and provides independent authority to the government to purchase end products (a) manufactured in the United States or (b) end products substantially transformed in the United States.

39. Earlier versions of the TA Clause limited the government's purchase of U.S. products to domestic end products as that term is used in the Buy American Act and defined in FAR 25.003. That term includes a product manufactured in the U.S. from foreign components, but imposes restrictions on the percentage of foreign components unless the product is a Commercial Off-the-Shelf item. Subsequently, the TA Clause evolved to permit the government to buy other U.S. manufactured products that are not within the definition of domestic end products, in addition to domestic end products. However, the narrower preference for U.S. products that qualify as domestic end products still applies when an acquisition is below the WTO GPA TA Clause threshold established by the FAR, including acquisitions subject to the Buy American Act and those to which multiple free trade agreements, but not the WTO GPA, apply. FAR 25.504-1; FAR 25.504-3; FAR 52.225-1 – Buy American – Supplies; FAR 52.225-3 – Buy American – Free Trade Agreements – Israeli Free Trade Act. The current TA Clause also permits the government to buy products substantially transformed in the United States, under the definition of U.S.-made end product, so that no product substantially transformed in the United States is disadvantaged compared to a product substantially transformed in a designated foreign country benefitting from a waiver under the TAA.

40. The current scope of U.S.-made products that can be purchased by the government when the TA Clause applies is illustrated by example in FAR 25.504-2 in which both U.S.-made domestic end products and U.S.-made non-domestic end products, as well as TAA eligible non-U.S.-made products, are required to be considered by the contracting officer. Excluding end products that are domestic end products when the TA Clause applies violates the FAR.

41. At all relevant times, Acetris' Entecavir Tablets product has been a U.S.-made domestic end product which may be procured by the government under all domestic preference rules, including the TA Clause.

42. The FAR requires inclusion in commercial item contracts of the standard Trade Agreements Certificate in the Offeror Representations and Certifications—Commercial Items Clause at 52.212-3(g)(5)(iii), which states that:

> *The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.*

The Solicitation and Related Procurement Background

43. Acetris currently holds a VA National Contract ("the Existing Contract"), Contract No. VA797P-17-C-0011, which is a requirements contract, for the supply of Entecavir Tablets. Complaint Ex. 3, Existing Entecavir Contract.

44. The Existing Contract was effective April 13, 2017 and has a base year running through April 12, 2018 as well as four one year options. Currently, the Existing Contract is in the base year and, unless the next option is exercised or the contract is extended, will expire on April 13, 2018. *Id.*

45. The Existing Contract contains the standard TA Clause and as well as the Trade Agreement Certificate, FAR 52.212-3, both of which also are contained in the Solicitation subject to this protest. *Id.* at 30, 75.

46. On June 6, 2017, the VA issued a cure notice threatening to terminate Acetris' Existing Contract for default unless Acetris sought "an advisory determination from the U.S. Customs and Border Protection ["CBP"] in accordance with 19 C.F.R. § 177 Subpart B - Government Procurement." Complaint Ex. 4, Cure Notice, at 2.

47. The cure notice was the culmination of a series of exchanges between the parties in which the VA "demanded that Acetris provide a compliance letter that followed the definition of substantial transformation under the TAA, as set forth in FAR 52.225-5." *Id.* Acetris replied that its products were U.S.-made end products, not foreign products, because each was "an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States" as defined in the U.S.-made end product prong of the TA Clause. *Id.*

48. The basis for the cure notice was the VA's mistaken belief that, applying the TA Clause of the Company's contract, "[u]nder TAA standards, the test that is utilized to determine an end product's country of origin is substantial transformation," entirely reading out the separate "manufactured in the United States" criterion in the definition of U.S.-made end product in the TA Clause. *Id.* at 1 (emphasis added).

49. Having impermissibly narrowed FAR 52.225-5, the VA further stated that "[w]ithin the entire federal Government, the United States Custom and Border Protection (CBP) is the sole federal entity with authority to make country of origin determinations for TAA

purposes," thus washing its hand of any responsibility for interpreting and implementing procurement regulations and the TA Clause. *Id.* at 1-2.

50. On July 7, 2017, Acetris submitted a request for Final Determination to U.S. Customs and Border Protection ("CBP").

51. On January 30, 2018, CBP issued a Final Determination, published on February 5, 2018, in the Federal Register, opining that the active ingredient used in the manufacture of Entecavir Tablets, which was sourced from India (a fact not in dispute), did not undergo a change in name, character or use; that therefore no substantial transformation occurred in the United States; and that therefore Entecavir Tablets were considered a product of India. CBP also opined that Entecavir Tablets are not manufactured in the United States because they were not "wholly" manufactured in the United States, components included, applying the test set forth in CBP's regulations at 19 C.F.R. 177.22(a) used to determine whether a foreign product is eligible for a TAA waiver. Acetris timely appealed this determination to the Court of International Trade. 83 FR 5118, 5132-33.

52. On February 5, 2018, Acetris filed a CDA claim with the VA, requesting that the contracting officer issue a final decision interpreting the "U.S.-made end product" definition in the TA Clause to include products manufactured in the United States based on the first criterion without regard to whether the products were substantially transformed in the U.S. under the alternate criterion. Complaint Ex. 5, CDA Claim.

53. On February 22, 2018, the VA contracting officer transmitted to Acetris a second cure notice stating that, because of CBP's final determination regarding Acetris' Entecavir Tablets product, termination for cause procedures would be issued unless Acetris within

15 days provided the VA with a source for Entecavir Tablets that was Trade Agreement Act compliant, citing 19 C.F.R. § 177.21 *et seq.* Complaint Ex. 6, Second Cure Notice.

54. Acetris and the VA conducted a telephonic meeting regarding the VA's February 22, 2018 letter and Acetris' claim on March 6, 2018. Complaint Ex. 7, Declaration of Mark Chirico.

55. In the meeting, the VA (a) asserted that it did not intend to issue a formal contracting officer's decision on Acetris' claim; (b) reiterated its position that, absent a federal court decision to the contrary, its policy is to rely entirely on CBP's Final Determinations in determining whether it can acquire products under the TA Clause, (c) stated that it could not purchase a product that was manufactured in the U.S. unless it also was substantially transformed in the U.S. or a designated country, because in its view such products were not TA Clause compliant; and stated that Acetris' Entecavir Tablets were not TA Clause compliant because CBP opined that the active pharmaceutical ingredient used in manufacturing the end product, which was sourced from India, was not substantially transformed in the U.S. manufacturing of Entecavir Tablets. *Id.*

56. On March 8, 2018, the VA contracting officer transmitted to Acetris a letter indicating it was allowing Acetris until March 26, 2018, to provide a "TAA compliant source." Complaint Ex. 8 (emphasis added). The letter required that Acetris provide a letter of supply from the new supplier stating that the end product was Trade Agreement Act compliant and disclosing the country of origin of the active pharmaceutical ingredient. *Id.* The letter also stated, "[a]s of March 26th, it is the VA's intention to no longer purchase the current Acetis [sic] products." *Id.*

57. On March 9, 2018, the VA issued a public pre-solicitation notice indicating its intent to issue Request for Proposal (RFP) 36E79718R0019 for an unrestricted procurement for Entecavir Tablets for the VA, the Department of Defense, the Bureau of Prisons, and the Indian Health Service. Complaint Ex. 9, Pre-Solicitation Notice.

58. On March 14, 2018, the VA issued the Solicitation, which is the subject of this protest, for a new requirements contract for Entecavir Tablets, with a base period of one year and four one-year options. Complaint Ex. 1, Solicitation.

59. The Solicitation contained the standard TA Clause which was expressly incorporated by reference through the Solicitation's Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items at FAR 52.212-5(b)(48), *Id.*at 30, and the standard Trade Agreements Certificate which was included through the Solicitation's Offeror Representations and Certifications—Commercial Items Clause at 52.212-3(g)(5)(iii), *id.* at 61, stating that:

> *The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.*

60. However, in three places in the Solicitation, the VA inserted a separate re-written version of this provision, applying the VA's improper interpretation of the clause contrary to the FAR and indicating the VA's intent impermissibly to treat Acetris' products as non-compliant. Specifically, the Solicitation stated that:

> *[i]f the Contracting Officer determines that there are no offers for such products sourced from countries that are Trade Agreement Act (TAA) compliant, then the Contracting Officer may determine to consider products not covered by the Trade Agreement Act (TAA) pursuant to FAR Part 25.*

Id. at 5, 51, and 72 (emphasis added.)

61. Further, the Solicitation required that, for dealers and suppliers, "[i]n addition to identifying Country of Origin for the end product offered under this solicitation in accordance with contract clause 52.212-3 Offeror Representation and Certifications, the offeror shall also identify the Country of Origin for all active pharmaceutical ingredients (APIs). Offerors shall certify whether or not the end product(s) offered in response to this solicitation are from the United States or a Trade Agreement Act (TAA) qualifying or designated country." *Id.* at 51.

62. The FAR contains no requirement that offerors of pharmaceutical end products identify the country of origin of the component active and inactive ingredients used in manufacturing such end products. Such information is unrelated to whether such a product is a U.S.-made end product manufactured in the United States, and this information serves only to permit the VA improperly to decide that U.S.-made pharmaceutical end products incorporating active ingredients from a non-designated country do not comply with the TA Clause.

63. Finally, the Solicitation stated that "**[m]anufacturers must also certify whether or not the end product offered in response to this solicitation is TAA compliant. Offers that fail to meet this requirement before contract award shall be rejected and shall receive no further consideration**." *Id.* at 51 (emphasis in original).

64. Acetris' manufacturer, Aurolife, has certified that the Entecavir Tablets it supplies to Acetris are manufactured in the United States and thus qualify as U.S.-made end products, but it cannot certify that these products are foreign products that are wholly

the manufacture of, or substantially transformed in, a designated country pursuant to the TAA. Complaint Ex. 7, Declaration of Mark Chirico.

65. On March 15, 2018, Acetris submitted five questions to the contracting officer responsible for the Solicitation. Complaint Ex. 7, Declaration of Mark Chirico; Complaint Ex. 10, 3/15/18 Email from M. Chirico to Contracting Officer. On March 21, 2018, the contracting officer responded to these questions. Complaint Ex. 11, 3/21/18 Email from Contracting Officer to M. Chirico. The five questions and answers are set forth below.

66. "1. The solicitation states on page 5 and 51 that the Government will evaluate offers in accordance with the policies and procedures of FAR Part 25, and will only consider offers of "U.S.-made or designated country end products" for award. FAR 25.003 defines "U.S.-made end product" for purposes of FAR Part 25 as a product that is manufactured in the U.S. or is substantially transformed in the U.S. into a new article of commerce. Will the VA consider offers of "Entecavir Tablets" – the products solicited – to be offers of "U.S.-made end products" under the first criterion if the Entecavir Tablets are manufactured in the U.S. from an active chemical ingredient manufactured in India?" *Answer: Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B): An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.*

67. "2. The solicitation states on page 51 that offerors that are not manufacturers must submit a letter of commitment from the manufacturer, and that the manufacturer must also certify whether or not the product offered in response to the solicitation is "TAA compliant." By "TAA compliant" does the VA mean the product offered is either a U.S.-made or designated country end product as both terms are defined in FAR Part 25?" *Answer: The letter must disclose the country of origin of the API and the [sic] confirm it is TAA compliant.*

68. "3. The solicitation states on page 51 that the offeror must not only identify country of origin of the offered end products in accordance with FAR 52.212-3 Offeror Representations and Certifications (incorporated in the solicitation), but also must identify country of origin of all active pharmaceutical ingredients (API) in the end products, and must "certify whether or not the end product(s) offered are from the United States or a Trade Agreement Act (TAA) qualifying or designated country." Does the phrase "end product(s) offered are from the United States" mean that end products offers are "U.S.-made end products" as defined in FAR Part 25 and if a manufacturer identifies the country of origin of API as a non-designated country, will the VA still consider an offer of Entecavir Tablets compliant if the tablets are manufactured in the United States?" *Answer: In clause 52.212-3 there is a section to disclose the country of origin. Also, the interested company that is not the manufacture [sic] must produce a Letter of Commitment prior to award.*

69. "4. The solicitation states at pages 5 and 51 that the Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. FAR subpart 25.5 governs evaluation of foreign offers in supply contracts, and FAR 25.504-2 "WTO

GPA/Caribbean Basin Trade Initiative/FTAs" states there are two categories of offers of "US-made end products": those that offer domestic end products and those that offer products that are not domestic end products but otherwise meet the definition of U.S.-made end product, and both may be considered in an acquisition covered by the WTO-GPA. Will the VA consider offers of products manufactured in the U.S. that qualify as domestic end products as defined in FAR Part 25 to be "U.S.-made end products" for purposes of the solicitation, whether or not they qualify as U.S.-made end products under the substantial transformation criterion?" *Answer: If the manufacture of the drug is not TAA compliant and there are no TAA offers received then the Government may take Non-TAA offers. The substantial determination is determined by U.S. Customs and Border Protection. The Buy American Act is under $190,000 and the Trade Agreement Act is $190,000 and above.*

70. "5. Will the VA consider "Entecavir Tablets" currently offered under VA 797P-17-C-0011 that are manufactured in the U.S. to be US-made end products as defined in FAR Part 25, even if Customs and Border Patrol has determined under its rules for determining if a product is a product of a designated country that the tablets are a product of India?" *Answer: U.S. Customs and Border Protection's determination is final and cannot be overturned. The API was manufactured in India and India is deemed Non-TAA compliant.*

V. GROUNDS OF PROTEST

COUNT I

71. Paragraphs 1 through 70 are incorporated by reference as though fully set forth therein.

72. The TA Clause permits the government to purchase and contractors to deliver U.S.-made end products based solely on the first criterion in the definition: the end products are manufactured in the United States. Such products are compliant with the requirements of the TA Clause.

73. Section 13 of the Solicitation defines place of manufacture of drug products in the form of capsules or tablets as the location of the facility where ingredients are measured, weighed, mixed and compounded. For Acetris' Entecavir Tablets, these processes occur in New Jersey. All of the processes required to manufacture Acetris' Entecavir Tablets occur at Aurolife's facility in Dayton, New Jersey.

74. The VA improperly interprets the TA Clause contained in the Solicitation as prohibiting purchase of Acetris' Entecavir Tablets, which are manufactured in the United States, unless the VA makes a non-availability determination that no TAA compliant products are available, even though FAR mandates that a non-availability determination consider the availability of both U.S.-made end products and designated country end products.

75. Acetris' Entecavir Tablets are domestic end products, which are a subset of U.S.-made end products that must be given a preference when the Buy American Act applies. Contrary to FAR 25.504-1, FAR 25.504-2, FAR 25.504-3, and FAR 52.225-5, the VA's interpretation of the TA Clause irrationally excludes from consideration for award domestic end products that could be purchased if the acquisition was under the WTO GPA threshold for application of the TA Clause and are also included within the definition of U.S.-made end products that can be purchased under the TA Clause.

76. The VA's interpretation of the Solicitation is contrary to law, arbitrary and capricious.

77. The VA's interpretation of the Solicitation, unless enjoined, will cause irreparable harm to Acetris.

78. Accordingly, Acetris is entitled to a declaration that the TA Clause permits purchase of U.S.-made end products that are manufactured in the U.S. even if CBP has stated that the active pharmaceutical ingredient used, along with inactive ingredients, in the manufacture of the products, is from India and not "substantially transformed" in the manufacturing process.

79. Acetris also is entitled to an injunction prohibiting the VA from interpreting the TA Clause of the Solicitation as prohibiting purchase of U.S.-made products manufactured in the U.S., including the Company's Entecavir Tablets.

COUNT II

80. Paragraphs 1 through 79 are incorporated by reference as though fully set forth therein.

81. Under the TA Clause and the Trade Agreements Certificate in FAR 52.212-3, the government can purchase, without a non-availability determination, an article if it is either a U.S.-made product manufactured in the United States or substantially transformed in the United States or a designated country end product wholly manufactured or substantially transformed in a designated country, and is required to evaluate offers of all such products. The TA Clause differentiates between the two categories of acceptable end products because the United States is not a TAA country granted a waiver of the procurement preference for domestic products. Acetris' manufacturer, Aurolife, has certified that the Entecavir Tablets it supplies to Acetris are manufactured in the United States, and thus qualify as U.S.-made end products, but it

cannot certify that these products are foreign products that are wholly the manufacture of, or substantially transformed in, a designated country pursuant to the TAA.

82. The VA Solicitation requirement that "[m]anufacturers must also certify whether or not the end product offered in response to this solicitation is TAA compliant" and statement that "[o]ffers that fail to meet this requirement before contract award shall be rejected and shall receive no further consideration" unduly restricts offers to products of TAA countries, excludes products manufactured in the U.S., which is not a TAA country, and is arbitrary and capricious, an abuse of discretion and in violation of the FAR.

83. Accordingly, Acetris is entitled to a declaration that the VA's Solicitation is defective, arbitrary and capricious and violates the FAR.

84. Acetris also is entitled to an injunction prohibiting the VA from proceeding with the contemplated procurement through a Solicitation that mandates rejection of any offer for which the manufacturer has not certified TAA compliance where the offered product is a U.S.-made product manufactured in the United States.

COUNT III

85. Paragraphs 1 through 84 are incorporated by reference as though fully set forth therein.

86. Under the TA Clause, the government can purchase, without a non-availability determination, an article if it is either a U.S.-made end product manufactured in or substantially transformed in the U.S. or a designated country end product wholly the manufacture of or substantially transformed in a designated country. The different standard for U.S.-made end products in the TA Clause is purposeful. The term is intended to relax the more restrictive domestic component requirement for domestic end

products in procurements to which the TA Clause applies and encompass all products manufactured in the U.S. regardless of component country of origin.

87. Under the FAR, only the contracting officer has the authority to interpret the provisions of a contract, including the TA Clause, and applicable procurement regulations. FAR Part 25 does not require the contracting officer to defer to or even seek a determination from CBP regarding any aspect of the TA Clause, much less with respect to the "manufactured in the United States" criterion in the definition of U.S.-made end product which is separate, and not derived, from the TAA.

88. The VA relies entirely on CBP determinations of country of origin of foreign products under the Trade Agreements Act in determining whether a product complies with the TA Clause, including whether the product is a U.S.-made end product.

89. In particular, the VA performs no assessment, separate from CBP's determination of whether a product is a designated country end product, of whether a product is a U.S.-made end product manufactured in the United States under the TA Clause. The VA will not decide that an end product is manufactured in the United States even if the stated place of manufacture under the Solicitation terms is the United States.

90. The VA's refusal to interpret and give full effect to the U.S.-made end product provision of the TA Clause is arbitrary and capricious, an abuse of discretion and contrary to FAR.

91. The VA's refusal to interpret and give full effect to the U.S.-made provision of the TA Clause, unless enjoined, will cause irreparable harm to Acetris.

92. Accordingly, Acetris is entitled to a declaration that the TA Clause's standard for determining a U.S.-made end product based on the "manufactured in the United States"

criterion is separate and different from the standard in CBP's regulation, and permits the government to purchase U.S.-made end products manufactured in the U.S. from foreign components.

93. Acetris is entitled to a declaration that the VA's refusal to interpret and give full effect to the U.S.-made end product provision of the TA Clause, in complete reliance on CBP, is an abdication of its responsibility to interpret the contract terms, arbitrary and capricious, an abuse of discretion and contrary to FAR.

94. Acetris also is entitled to an injunction prohibiting the VA from relying solely on CBP to interpret the TA Clause and refusing to interpret and give full effect to the definition of U.S.-made end product in the TA Clause and the first alternative criterion under that definition: the product is manufactured in the United States.

PRAYER FOR RELIEF

Wherefore, plaintiff Acetris Health, LLC, respectfully prays that this Court enter judgment in its favor and against Defendant, and to provide the following relief:

1. A declaration that the TA Clause permits purchase of U.S.-made end products that are manufactured in the U.S. even if CBP has stated that the active pharmaceutical ingredient used, along with inactive ingredients, in the manufacture of the products, is from India and not "substantially transformed" in the manufacturing process.
2. An injunction prohibiting the VA from interpreting the TA Clause of the Solicitation as prohibiting purchase of U.S.-made products manufactured in the U.S., including the Company's Entecavir Tablets.
3. A declaration that the VA's Solicitation is defective, arbitrary and capricious and violates the FAR.

4. An injunction prohibiting the VA from proceeding with the contemplated procurement through a Solicitation that mandates rejection of any offer for which the manufacturer has not certified TAA compliance where the offered product is a U.S.-made product manufactured in the United States.
5. A declaration that the TA Clause's standard for determining a U.S.-made end product based on the "manufactured in the United States" criterion is separate and different from the standard in CBP's regulation, and permits the government to purchase U.S.-made end products manufactured in the U.S. from foreign components.
6. A declaration that the VA's refusal to interpret and give full effect to the U.S.-made end product provision of the TA Clause, in complete reliance on CBP, is an abdication of its responsibility to interpret the contract terms, arbitrary and capricious, an abuse of discretion and contrary to FAR.
7. An injunction prohibiting the VA from relying solely on CBP to interpret the TA Clause and refusing to interpret and give full effect to the definition of U.S.-made end product in the TA Clause and the first alternative criterion under that definition: the product is manufactured in the United States.
8. Any other relief this Court deems proper.

Date: March 23, 2018

Respectfully Submitted,

s/Stephen E. Ruscus_____

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CERTIFICATE OF SERVICE

I certify that I have caused a true and accurate copy of the Complaint to be delivered by the delivery method indicated below the 23th day of March, 2018 to the following:

United States Department of Justice *(via electronic mail)*
Commercial Litigation Branch
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Tel: (202) 616-0475
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s/Stephen E. Ruscus
Stephen E. Ruscus

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